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07 CIV 8434

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

- x

THE PEOPLE OF THE STATE OF NEW YORK, by ANDREW M. CUOMO, Attorney General of the State of New York, and THE CITY OF NEW YORK,

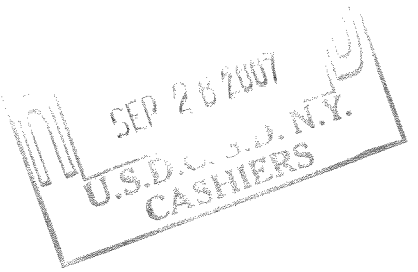
Plaintiffs,

-against-

MERCK & CO., INC.,

Defendant.

- x



No.:

NOTICE OF REMOVAL OF DEFENDANT MERCK & CO., INC.

PLEASE TAKE NOTICE that Defendant Merck & Co., Inc. ("Merck"), through undersigned counsel, hereby removes the above-captioned action from the Supreme Court of the State of New York, County of New York, to the United States District Court for the Southern District of New York, pursuant to 28 U.S.C. §§ 1331 and 1441. In support of its removal, Merck respectfully states as follows:

1. This action involves allegations regarding the prescription drug Vioxx®. An MDL proceeding, *In re Vioxx Marketing, Sales Practices and Products Liability Litigation,* MDL No. 1657, has been established in the United States District Court for the Eastern District of Louisiana (Fallon, J.) for coordinated pretrial proceedings of Vioxx-related actions pursuant to

28 U.S.C. § 1407. Six other suits regarding state Medicaid payments for Vioxx have been filed in Louisiana, Mississippi, Alaska, Montana, Utah, and Colorado and are already pending in that MDL proceeding.[1] Because the subject matter of this suit, which involves Medicaid payments by the State of New York for the drug Vioxx, is the same as the six suits already in the MDL proceeding, Merck likewise will seek the transfer of this action to that MDL.

2. On September 17, 2007, New York Attorney General Andrew M. Cuomo, on behalf of the People of the State of New York, and the City of New York commenced this action in the Supreme Court of the State of New York, County of New York, against Merck, captioned *The People Of The State Of New York, by Andrew M. Cuomo, Attorney General of the State of New York, and the City Of New York v. Merck & Co., Inc.*, No. 07/406439. A true and correct copy of Plaintiffs' Complaint ("Compl.") is attached as Exhibit A. Merck was served with a copy of the Complaint on September 18, 2007. Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b).

3. Venue is proper in this Court pursuant to 28 U.S.C. § 112(b), because it is the "district and division embracing the place where such action is pending." 28 U.S.C. § 1441(a).

4. No previous application has been made for the relief requested herein.

5. Merck will promptly (a) file a true and correct copy of this Notice of Removal with the Clerk of Court for the Supreme Court of the State of New York, County of New York in accordance with 28 U.S.C. § 1446(d); and (b) serve Plaintiffs' counsel with a true and correct copy of this Notice of Removal, in accordance with 28 U.S.C. § 1446(d).

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[1] The five Medicaid actions in the MDL are *Foti v. Merck & Co., Inc.*, No. 05-3700 (E.D. La.) (Louisiana), and *Hood v. Merck & Co., Inc.*, No. 05-6755 (E.D. La.) (Mississippi), *Alaska v. Merck & Co., Inc.*, No. 06-3132 (E.D. La.) (Alaska), *Montana v. Merck & Co., Inc.*, No. 06-4302 (E.D. La.) (Montana); *Utah v. Merck & Co. Inc.*, No. 06-9336 (E.D. La.) (Utah); and *Franklin on behalf of the State of Colorado v. Merck & Co., Inc.*, No. 07-2073 (E.D. La.) (Colorado).

6. Plaintiffs' six-count complaint alleges that Merck "has engaged in repeated and persistent fraud and has caused false and fraudulent claims to be submitted to the New York State Medical Assistance Program ('Medicaid') and the Elderly Pharmaceutical Insurance Coverage ('EPIC') program by suppressing, misrepresenting and concealing material information in its communications with doctors and patients concerning the seriousness of the cardiovascular risks associated" with Vioxx. (Compl. ¶ 1.)

7. Plaintiffs seek to permanently enjoin Merck "from engaging in the type of repeated or persistent fraudulent and unlawful practices" alleged and further seeks an order requiring Merck to pay restitution and damages to all aggrieved consumers and the State of New York. (Compl., Prayer for Relief.) Plaintiffs also seek, *inter alia*, treble damages, costs, expenses, attorneys' fees, and "all other relief that is just and proper." (*Id.*)

8. This Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. § 1331 because Plaintiffs' claims directly implicate two areas of federal law: the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, which regulates prescription drug manufacturers' public and promotional statements about prescription drugs; and federal Medicaid law, which determines both which drugs a state must cover under its Medicaid program and the limited circumstances under which it can decline to pay for such drugs. *See* 42 U.S.C. §§ 1396r-8(d)(1)(B), (d)(4). Thus, this action may be removed to this Court pursuant to 28 U.S.C. § 1441.

9. The Supreme Court has recognized that federal question jurisdiction exists over claims that are asserted under state law if the state law claims implicate substantial federal questions. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314-15

(2005); *Hopkins v. Walker*, 244 U.S. 486, 489-91 (1917); *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1025 (N.D. Cal. 2005).

10. As the Supreme Court explained in *Grable*, the test for whether a federal court should hear a case under this doctrine is not whether the federal statute provides a parallel private right of action, but whether the "state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 314. In *Grable*, the Supreme Court concluded that federal question jurisdiction existed because the plaintiff's state law claim was premised on the failure of a government agency to fulfill its responsibilities as defined by federal law. Accordingly, the interpretation of federal law was essential to resolving the state law claim. *Id.* at 314-15. The same is true here.

11. ***First***, the claim in this case is implicitly and explicitly premised upon alleged violations of the ***federal*** Food, Drug & Cosmetic Act ("FDCA"), specifically, that Merck illegally promoted an unsafe drug for public use and failed to warn doctors and state regulators of risks in violation of FDCA rules and regulations.

12. Under the FDCA, the FDA is tasked with approving drugs for human use and determining the necessary warning manufacturers must include with their products. 21 U.S.C. § 393(b). The FDCA charges the FDA to ensure that "drugs are safe and effective" for their intended uses, *id.* § 393(b)(2)(B), in part by "promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products." *Id.* § 393(b)(1). The FDA is vested with the authority to promulgate regulations to enforce the FDCA, which are codified in the Code of Federal Regulations, 21 C.F.R. § 200 *et seq.*; 21 U.S.C. § 371(a).

13. To accomplish this mandate, the FDA maintains a Center for Drug Evaluation and Research ("CDER"). The CDER oversees the drug companies' development, testing and research, and manufacture of drugs. The staff of approximately 1,800 examines clinical and other testing data generated by drug companies to assess a drug's benefits against its risks and to make an approval decision. In addition to regulating prescription drug advertising generally, the CDER also oversees the Package Inserts that outline benefit and risk information, and monitors marketed drugs for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. Indeed, under federal law, even claims in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4).

14. The centrality of federal food and drug law to the allegations at issue in this matter are evidenced by Plaintiffs' own complaint, which repeatedly cites the FDA's oversight of the highly regulated representations at issue in the case. *See, e.g.*, Compl. ¶ 2 (noting FDA[2] approval of Vioxx and its relationship to the ability to market Vioxx); *id.* ¶¶ 29-30 (noting the oversight role played by both FDA Advisory Committees and the FDA itself).

15. ***Second***, Plaintiffs' claim for recovery of monies spent by the State of New York on Vioxx necessarily implicates federal laws and regulations related to Medicaid because it depends on the interpretation and application of federal statutory provisions that govern what can be included in or rejected from state Medicaid formularies, including New York's. In addition, federal funds comprise half of the funds at issue in this lawsuit, i.e., money spent for Vioxx under the New York Medicaid Program, and any health benefits that the State of New York has

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[2] While Plaintiffs assiduously avoided referencing the FDA in describing the indications for which Vioxx was "approved" for marketing in 1999, the ability to market a prescription drug such as Vioxx is obviously contingent on approval from that agency.

paid or will pay as a result of alleged Vioxx-related injuries among Medicaid recipients.[3] *See* Compl. ¶ 14 (New York "Medicaid[] is jointly funded by the Federal, State, and local governments").

17. The federal Medicaid program authorizes federal money grants to states to provide medical assistance to low-income individuals. *See* 42 U.S.C. § 1396 *et seq.*; 42 C.F.R. § 430.10 *et seq.* "Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the [Medicaid] Act and regulations promulgated by the Secretary of Health and Human Services . . . ." *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990). *See also Westside Mothers v. Haveman*, 289 F.3d 852, 858 (6th Cir. 2002) ("[T]he conditions imposed by the federal government pursuant to statute upon states participating in Medicaid and similar programs are not merely contract provisions; they are federal laws."). In New York, the Medicaid program is administered by the New York State Department of Health, which is required under federal law, 42 U.S.C. § 1396a, to submit a Medicaid plan which attests to the state's compliance with federal statutes and regulations. *See* 42 C.F.R. § 430.10 ("The State plan is a comprehensive written statement submitted by the [state Medicaid] agency . . . giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances . . . ."). Moreover, federal law mandates both the eligibility requirements for recipients of medical assistance and the types of medical services that must be provided if a state chooses to administer a Medicaid program. 42 U.S.C. § 1396d. *See also Coe v. Hooker*, 406 F. Supp. 1072, 1079 (D.N.H. 1976) (under the Medicaid program, the federal government "will share with the states

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[3] For fiscal year 2004 (October 1, 2003 to September 30, 2004), for example, federal funds accounted for 50% of New York's Medicaid financing. *See Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the State Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2003 Through September 30, 2004*, 67 Fed. Reg. 69,223, 69,224 (Nov. 15, 2002).

the cost of any medical service offered in the state programs so long as the service comes within any of the seventeen enumerated categories of medical care" in § 1396d).

18. In addition, federal law expressly requires states, subject to certain narrow exceptions, to reimburse FDA-approved prescription drugs of any manufacturer that has entered into and complies with a rebate agreement with the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8. Thus, New York is required under federal law to reimburse companies like Merck for the drugs that it reimburses under its state program if the manufacturer has complied with federal requirements.

19. Indeed, the sole time that a state can exclude from its formulary an outpatient drug that is covered by a federal rebate agreement is "with respect to the treatment of a specific disease or condition for an identified population . . . only if, based on the drug's labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion." 42 U.S.C. § 1396r-8(d)(4)(C). But even in such a situation, a state cannot deny coverage altogether; rather, a state must condition such reimbursement on prior authorization, meaning that the state may require that it approve reimbursement before the drug is dispensed. *Id.* § 1396r-8(d)(4)(D). And even a decision to require prior authorization must satisfy federally mandated requirements. *Id.* §§ 1396r-8(d)(5). Thus, every step a state takes with regard to coverage of an FDA-approved drug is subject to strict federal mandates.

20. To summarize, because New York's Medicaid program operates within this overarching federal statutory and regulatory framework, Plaintiffs' claims alleging that Merck's conduct concerning Vioxx caused the State of New York to spend money on Vioxx and

allegedly Vioxx-related injuries necessarily turns on substantial questions of federal Medicaid law.

21. Other courts have recognized that federal jurisdiction exists under *Grable* over actions, like this one, in which plaintiffs' state law claims are premised on violations of the FDCA and cases in which plaintiffs seek reimbursement of Medicaid expenditures. For example, in *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the court asserted federal question jurisdiction over state-law claims brought by the state of Louisiana involving a manufacturer's marketing of a prescription drug and the state of Louisiana's payments for that drug under Medicaid, finding that state attorney general's claims involved "a core of substantial issues [that were] federally oriented." *Id.* at 172-73.

22. Likewise, in a recent case involving Medicaid drug pricing, the court in *County of Santa Clara* held that federal jurisdiction was proper under *Grable* because the plaintiff's state law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1031 (N.D. Cal. 2005). In concluding that the Medicaid drug pricing issues merited federal jurisdiction, the court observed that one measure of evaluating substantiality is "the importance of the federal issue," and noted that "[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme." *Id.* at 1027.

23. In short, Plaintiffs' claims here implicate two complex federal regulatory schemes: the federal FDCA and federal Medicaid law. Accordingly, as in *Grable, Zyprexa*, and *Astra USA*, Plaintiffs' allegations will necessarily require the Court to address substantial

questions of federal law, and the Court therefore has federal question jurisdiction over this matter.

24. WHEREFORE, Defendant Merck respectfully removes this action from the Supreme Court of the State of New York, County of New York, to this Court pursuant to 28 U.S.C. § 1441.

DATED: New York, New York
September 28, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

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Attorneys for Defendant Merck & Co., Inc.

Exhibit A

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, by ANDREW M. CUOMO, Attorney General of the State of New York, and THE CITY OF NEW YORK,

Plaintiffs,

- against -

MERCK & CO., INC.,

Defendant.

COMPLAINT
Index No. 07/406439

TO: THE SUPREME COURT OF THE STATE OF NEW YORK

The People of the State of New York, by their attorney, Andrew M. Cuomo, Attorney General of the State of New York, and The City of New York, by its attorney, Michael A. Cardozo, Corporation Counsel of the City of New York, allege the following upon information and belief:

PRELIMINARY STATEMENT

1. Merck & Co., Inc. ("Merck") is a pharmaceutical manufacturer with pharmaceutical sales of billions of dollars each year. Merck has engaged in repeated and persistent fraud and has caused false and fraudulent claims to be submitted to the New York State Medical Assistance Program ("Medicaid") and the Elderly Pharmaceutical Insurance Coverage ("EPIC") program by suppressing, misrepresenting and concealing material information in its communications with doctors and patients concerning the seriousness of the cardiovascular risks associated with Merck's drug Vioxx (rofecoxib).

2. Merck began to market Vioxx in 1999. Vioxx is a non-steroidal anti-inflammatory drug ("NSAID") of a type known as COX-2 inhibitors. It was initially approved to treat the symptoms of osteoarthritis, acute pain in adults, and dysmenorrhea (painful menstruation), and was eventually indicated for rheumatoid arthritis, migraine headaches, and juvenile rheumatoid arthritis. Between 1999 and 2003, over 90 million prescriptions for Vioxx were dispensed in the United States.

3. New York Medicaid and EPIC have paid over $100 million for Vioxx since it entered the market in 1999. Tens of millions of these dollars were paid for Vioxx prescriptions and refills for patients with pre-existing cardiovascular risk factors.

4. Between 2001 and 2004, New York consumers spent millions of dollars on Vioxx.

5. Merck withdrew Vioxx from the market in September 2004 because of its excessive cardiovascular risks, including the increased risk of heart attack and stroke. Merck stated that it had concluded that the withdrawal was "the responsible course to take."

6. Before removing Vioxx from the market, Merck undertook a concerted and tenacious campaign of false and fraudulent statements to minimize the import and seriousness of any reports about the possible association between Vioxx and serious cardiovascular events, especially myocardial infarction ("heart attacks").

7. Merck tried to distort each negative disclosure about Vioxx. Its responses, aimed at doctors and consumers, misrepresented the true picture of the danger to patients who took Vioxx, especially the danger posed to patients with established coronary artery disease. Merck cherry-picked the outcomes from its own research, omitting material information that would have communicated Vioxx's real cardiovascular dangers.

8. As a result of Merck's disinformation campaign, which continued until just one month before Merck withdrew Vioxx from the market, New York physicians wrote and continued to write prescriptions for Vioxx that they otherwise would not have written, specifically for patients with established coronary artery disease. Absent Merck's disinformation campaign, those consumers would not have purchased and taken Vioxx, and third-party payors, including Medicaid, would not have paid for Vioxx.

9. The Attorney General of the State of New York and the City of New York bring this action to prevent Merck from engaging in similar fraudulent and deceptive conduct in the future and to obtain damages and restitution for the consumers and government agencies defrauded by Merck, as well as penalties and costs.

JURISDICTION AND PARTIES

10. Andrew M. Cuomo is the Attorney General of the State of New York. He is authorized to institute all actions and proceedings in which the State is interested, N.Y. Executive Law § 63(1); to seek an order that enjoins repeated or persistent fraudulent or illegal business acts or practices and awards damages and restitution for such acts, N.Y. Executive Law § 63(12); to recover treble damages for overpayments of public funds obtained by means of false statements or other fraudulent schemes, N.Y. Social Services Law § 145-b(2); and to recover three times the amount of damages sustained by the state on account of Merck's false statements along with civil penalties of between $6,000 and $12,000 per violation pursuant to the New York False Claims Act, N.Y. Finance Law §§ 189, 190(1).

11. Plaintiff the City of New York, is a municipal corporation organized pursuant to the laws of the State of New York. During the relevant time period, New York State's Medicaid plan required that local social services districts, such as the City, pay one half of the costs for drugs covered by Medicaid, after first deducting the federal share. N.Y. Soc. Serv. L. § 368-a. The federal share is generally 50 percent of the cost, leaving the remaining 50 percent to be split equally between the State and the City.

12. Merck, a New Jersey corporation, is a pharmaceutical manufacturing and sales company with headquarters at 1 Merck Drive, Whitehouse Station, New Jersey. Merck regularly conducts business within the State of New York and derives substantial revenues from goods consumed in New York.

13. Venue is proper in this court under N.Y. CPLR § 503.

FACTUAL ALLEGATIONS

A. The Medicaid and EPIC Programs

14. The Medical Assistance Program in New York State, commonly referred to as Medicaid, is jointly funded by the Federal, State, and local governments, and was created to provide medical assistance and other benefits for low-income individuals and families. Medicaid reimburses medical care, services, and supplies which are medically necessary and appropriate, consistent with quality of care and generally accepted professional standards. Prescription drugs are included among the supplies and services reimbursed by Medicaid. In New York State, the Medicaid Program is administered by the New York State Department of Health.

15. EPIC is a voluntary New York State-funded and state-administered program that provides prescription drug coverage to lower income consumers who are 65 years of age or older and are not eligible for full Medicaid coverage. Individuals who choose to participate in the

program must pay a copayment for each drug purchased based on the price charged for the drug, with the remaining costs being reimbursed by the program.

B. Merck's Aggressive Promotion of Vioxx Despite Its Cardiovascular Risks

16. In May 1996, Merck announced that it was developing a selective COX-2 inhibitor, publicizing it as a miracle drug for arthritis sufferers. At the time, Merck faced patent expirations on three of its ten most successful drugs – Mevacor, Pepcid, and Prilosec – which represented approximately $4 billion a year in U.S. drug sales. At the same time, Merck faced significant competitive threats from pharmaceutical manufacturers Monsanto and Pfizer, which were, in combination, developing a competitive selective COX-2 inhibitor, Celebrex, scheduled to hit the market months ahead of Merck's COX-2 inhibitor, Vioxx.

17. In 1996, Merck announced the initiation of clinical trials for Vioxx. Ultimately, Merck proposed a large-scale, long-term, double-blind study of gastrointestinal toxicity in patients taking Vioxx. This study, called the Vioxx Gastrointestinal Outcome Research ("VIGOR"), was designed specifically to demonstrate the gastrointestinal superiority of Vioxx as compared to another NSAID, naproxen.

18. In the planning stages of VIGOR, Merck suspected that Vioxx might cause cardiovascular problems. On November 21, 1996, an internal Merck memorandum suggested that, because participants in trials would not be permitted to use aspirin during the study to moot the cardiovascular risks of Vioxx "there is a substantial chance that significantly higher rates" of cardiovascular problems would be seen in Vioxx patients.

19. On February 25, 1997, Merck scientist Briggs Morrison sent an internal e-mail about the design of the VIGOR study. In that e-mail, Morrison suggested that trial participants be allowed to take aspirin to avoid flagging the cardiovascular risks of Vioxx. Unless patients in the

Vioxx group could take aspirin, he warned, "without COX-1 inhibition [i.e., aspirin] you will get more thrombotic events and kill drug [sic]."

20. Merck researcher Alise Reicin, now a Merck Vice President for clinical research, responded in an internal Merck e-mail that Merck was in:

> . . . a no win situation! The relative risk of [adverse GI events with] even low dose aspirin may be high as 2-4 fold. Yet, the possibility of increased CV events is of great concern (I just can't wait to be the one to present those results to senior management!). What about the idea of excluding high risk CV patients – i.e. those that have already had an MI, CABG, PTCA? This may decrease the CV event rate so that a difference between the two groups would not be evident. The only problem would be – Would we be able to recruit any patients?

21. Despite the concerns about cardiovascular risks, from 1996 through 1998, Merck issued public statements that touted the efficacy and gastrointestinal safety of Vioxx. Merck's pre-release marketing campaign conveyed the uniform message that Vioxx provided safe and effective pain relief while omitting any mention of cardiovascular risks.

22. Merck galvanized its army of sales representatives. In the Merck's 1998 Annual Report, CEO Raymond Gilmartin wrote that "[i]n 1998, to prepare for the introduction of Vioxx, as well as to meet other marketing challenges, we began adding 700 new and talented professional representatives to our already strong U.S. sales force." In fact, during the time period at issue in this complaint, Merck assigned over 3,000 sales representatives across the country to engage in face-to-face discussions with physicians about Vioxx.

23. Merck also had a huge budget for targeting consumers. In 2000, Merck spent nearly $161 million on direct-to-consumer advertising for Vioxx — more than PepsiCo spent to advertise Pepsi Cola. Over the next few years, until it withdrew Vioxx from the market, Merck spent an unprecedented $100 million a year to continue to market Vioxx directly to consumers.

24. Merck marketed the drug by attempting to increase public demand by convincing consumers and medical professionals of Vioxx's purported superior safety profile – and effectiveness. Merck's message was clear: Vioxx provided gastrointestinal benefits while being as safe and effective as traditional NSAIDs.

C. A Merck Study Shows the Increased Cardiovascular Risk of Vioxx

25. In 2000, Merck completed the VIGOR study. This study had a large scale (over 8,000 patients), and a relatively long duration (median duration nine months). The focus of the study was whether patients with rheumatoid arthritis would experience fewer serious gastrointestinal problems with Vioxx as compared to naproxen, a generic pain reliever included in the over-the-counter product Aleve.

26. The final data from VIGOR showed that Vioxx posed a substantial increase in cardiovascular risk over naproxen. Although VIGOR excluded patients with a predisposition to developing serious cardiovascular problems, forty-five patients in the study, after taking Vioxx, suffered confirmed serious cardiovascular thrombotic adverse events, including cardiac events (sudden death, heart attack and unstable angina), cerebrovascular events (ischemic stroke and transient ischemic accident) and peripheral arterial and venous events, as compared to only nineteen patients in the study who took naproxen.

27. Neither VIGOR nor earlier studies conducted by Merck (the "osteoarthritis studies") were designed to assess the cardiovascular effect of Vioxx and other NSAIDs. Because VIGOR was a particularly robust study in number of patients and duration, well-grounded conclusions concerning the cardiovascular effects of Vioxx could be drawn from the study. VIGOR enrolled more patients than in all of the prior osteoarthritis studies combined. VIGOR's median duration (9 months) was considerably longer than the length of the osteoarthritis studies (more than three-fourths of the patients in these studies were enrolled for either six weeks or six

months). VIGOR also included a blinded, expert adjudication to confirm the nature and seriousness of all cardiovascular-related adverse events, while the earlier osteoarthritis studies did not.

28. The results of the VIGOR study showed that the relative risk of serious cardiovascular thrombotic events from Vioxx as compared to naproxen was highly statistically significant at the .002 level. Statistical significance in medical research defines a probability value of 0.05 or less as significant, that is, the likelihood that the results could have occurred by chance is 5% or less. The .002 level means that the relative incidence of heart attacks as between Vioxx and naproxen would only be expected to occur by chance two times in a thousand instances. When all the heart attacks are compared between the Vioxx and naproxen groups, the patients taking Vioxx had five times the risk of having a heart attack compared to patients taking naproxen.

29. An FDA Medical Review dated February 1, 2001, was presented to an FDA Advisory Committee which met on February 8, 2001, to consider the benefits and risks of Vioxx ("February 2001 Advisory Committee"). Advisory Committees made up of non-agency experts review technical materials presented by the FDA, pharmaceutical manufacturers and others concerning a particular issue in connection with a specific drug or class of drugs and make recommendations on these issues to the FDA. The Medical Review concluded that Merck's own analysis of cardiovascular adverse events from VIGOR "could lead one to conclude that naproxen, with a 51% risk reduction compared to rofecoxib [Vioxx] could be the preferred drug." (Emphasis in original.)

30. The February 2001 Advisory Committee found that physicians needed clear information, including the data from VIGOR, about Vioxx's serious cardiovascular risks in order to make appropriate treatment judgments for their patients. The FDA concurred in this judgment.

31. In March 2001, Merck filed a patent application for a combination of Vioxx with a thromboxane synthase inhibitor, which helps protect against cardiovascular problems caused by blood clots.

32. Had they been provided with an accurate analysis of the level of statistical significance or relative risk associated with Vioxx, physicians would not have prescribed Vioxx to patients with established coronary artery disease.

D. Merck Minimized Vioxx's Cardiovascular Risk Through a Campaign of Suppression and Misrepresentation

33. Beginning no later than April 2000, and continuing almost until Vioxx was pulled from the market in 2004, Merck engaged in a campaign to suppress, misrepresent, and conceal adverse cardiovascular data concerning Vioxx, including adverse data from VIGOR, in its communications to doctors and consumers, including New York doctors and consumers. Merck maintained this consistent pattern of fraudulent and deceptive conduct, which minimized the cardiovascular risk posed by Vioxx, in order to keep doctors prescribing this medication and to induce consumers to ask their doctors for it. Described below are examples of Merck's conduct that comprised its on-going pattern of deceptive, fraudulent and illegal conduct.

Merck Required its Sales Representatives to Misrepresent VIGOR's Negative Cardiovascular Data and Minimize Vioxx's Risk When Responding to Doctors' Questions

34. Merck undertook a campaign to counter each new revelation or analysis of the VIGOR cardiovascular data by providing doctors with distortions of those data. Until shortly before Vioxx was removed from the market in 2004, Merck directed all of its sales representatives with responsibility for selling Vioxx ("sales reps") to provide misinformation to doctors who asked questions about the negative cardiovascular safety information from VIGOR.

35. Merck called these directives to its sales reps "Obstacle Responses." These directives included scripts the sales reps were required to follow to overcome the "obstacles" to Vioxx sales created by descriptions of VIGOR's negative cardiovascular findings in medical journals and the press. The Obstacle Responses directed the sales reps not to deviate from Merck's script or to go beyond the limited information set out in the Obstacle Response when responding to doctors' concerns.

36. Using these Obstacle Responses, Merck successfully barraged doctors with its message that Vioxx was safe for patients without regard to whether they had a history of adverse cardiovascular events, thereby increasing the likelihood that doctors would hear the same misleadingly selective information during multiple sales calls.

37. Each of Merck's Obstacle Responses and similar communications, which were national in application, were transmitted to Merck's New York sales reps. Merck's New York sales reps, in turn, communicated the information Merck designated, and only that information, to New York doctors who treated New York patients.

38. In an April 28, 2000 Obstacle Response, Merck directed its sales reps to use a newly developed "Cardiovascular Card" to "respond to questions [from physicians] about the cardiovascular effects of VIOXX." However, this Cardiovascular Card was misleading to physicians because it contained no information from VIGOR. It dealt only with the much smaller scale, shorter duration, less rigorous osteoarthritis studies. The Cardiovascular Card, therefore, was intended to divert doctors' attention, and did divert their attention, from VIGOR's negative results to the less valid, but far more favorable, cardiovascular safety data from the osteoarthritis studies.

39. Merck also provided its sales reps with a "Roadmap to the CV Card." In the "Roadmap," Merck instructed its sales reps "[t]o ensure that the physician agrees that the

cardiovascular events seen with VIOXX in OA [osteoarthritis] clinical trials were low and similar to diclofenac and nabumetone [two other NSAIDs]." This sales presentation did not use valid comparisons or address VIGOR's finding of Vioxx's increased cardiovascular risks.

40. In another Obstacle Response dated May 1, 2000, Merck directed sales reps to respond to doctors' questions about Vioxx's cardiovascular risks, by giving only the percentage of patients in the Vioxx and naproxen groups in VIGOR who had had a heart attack (.5 percent and .1 percent, respectively), and omitting material facts: the number of patients enrolled in the study (over 8,000); the number of patients who had had a heart attack; and a measure of either the high statistical significance of these findings or the relative risk (a five-fold increase for Vioxx if all the patients who had a heart attack were counted). The sales reps were also told to guide the doctor through less valid and more favorable data from the osteoarthritis studies described on the Cardiovascular Card.

41. On May 22, 2001, citing the cardiovascular data from VIGOR, The New York Times published an article that led with the sentence, "Doctors are beginning to worry that Vioxx and Celebrex, two wildly popular arthritis drugs, may not be as safe as they were initially believed to be." On May 24, 2001, Merck sent its sales reps an Obstacle Response addressing this article. Again, Merck directed its sales reps to limit their answers to doctors' questions about VIGOR to the percentage of Vioxx and naproxen patients in VIGOR who had had a heart attack.

42. The sales reps were instructed to use their Cardiovascular Cards to show the data from the osteoarthritis studies. They were directed to tell doctors that the incidence of heart attack in these smaller, generally shorter studies was less than 0.01 percent with Vioxx and that cardiovascular mortality in 6,000 patients (without identifying the studies, which appear to have been the osteoarthritis trials) was Vioxx 0.1, NSAIDs 0.8 and placebo 0. A doctor hearing this generalized and conclusory information, as opposed to the actual findings of VIGOR, would be

unable to determine the relative cardiovascular risk posed by Vioxx compared to naproxen. Nor could this minimized extract of VIGOR's cardiovascular outcomes give a doctor sufficient information to evaluate the relative strength of the findings of the VIGOR and osteoarthritis studies based on their size and design.

43. On August 21, 2001, Merck communicated to all sales reps responsible for selling Vioxx in response to an article in the Journal of the American Medical Association ("JAMA"), a well regarded, widely read, peer-reviewed journal, which analyzed the cardiovascular data from VIGOR. The JAMA article reported that the incidence rate of serious cardiovascular thrombotic events in the Vioxx group, compared to the naproxen group, was highly statistically significant. The article compared the incidence of heart attacks among the VIGOR Vioxx group to the rate of heart attacks suffered by patients receiving a placebo in a very large meta-analysis and found it was statistically significant. The authors urged doctors to exercise caution in prescribing Vioxx for patients at risk of cardiovascular disease.

44. In its August 21, 2001 communication, Merck directed its sales reps when responding to questions doctors might raise concerning the JAMA article to use the May 1, 2000 Obstacle Response, which limited its information about the VIGOR study to the percent of patients in the Vioxx and naproxen groups who had had a heart attack.

45. Merck's message to doctors was unequivocal: Merck had the data it needed to evaluate Vioxx's cardiovascular risk, and its data "suggest[ed] that there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx." This statement was based on data from a purported internal Merck meta-analysis involving 28,000 patients, though the supporting data were not publicly available. The only data from VIGOR included in Merck's response to the JAMA article was the same information previously given concerning the percentage of VIGOR subjects who suffered heart attacks.

46. Merck also informed its sales reps, and by extension prescribing doctors, that the difference in the rate of heart attacks between Vioxx and naproxen patients "is consistent with the ability of naproxen to inhibit platelet aggregation," i.e., that naproxen acts in a manner similar to aspirin to prevent the blood from clotting and causing thromboses. There were, however, no adequate studies to support this hypothesis, and the magnitude of the effect Merck claimed for naproxen's supposed anti-platelet properties exceeded that seen in the literature for any other anti-platelet agents.

47. Merck also issued a "General Bulletin" sometime after September 17, 2001, which instructed its sales reps to respond to doctors' questions concerning the cardiovascular outcomes from VIGOR, and specifically, the higher rate of heart attacks for Vioxx than naproxen, by refusing to discuss VIGOR because it was not reflected on the label. Instead sales reps were to show doctors the results from the osteoarthritis studies, the same studies that were on the Cardiovascular Card.

48. On September 17, 2003, Merck issued another Obstacle Response directing how its sales reps were to respond to doctors' questions about an abstract presented at the 2003 annual meeting of the American College of Rheumatology. The abstract concerned a study funded jointly by Merck and Harvard University which showed that (a) the use of Vioxx increased the adjusted relative risk of cardiovascular events over the use of Celebrex, a competing NSAID, or no NSAID, (b) the most common dosage of Vioxx was associated with the highest risk, and (c) the risk may be highest in the first ninety days of Vioxx treatment, which could adversely affect new prescriptions and new sales. The Obstacle Response directed the sales reps to respond to questions about the cardiovascular findings in the 2003 abstract by stating: "First, Doctor, let me say that based on all of the data that are available, Merck stands behind the overall efficacy and safety profile of Vioxx." This statement was misleading because it suggested that Merck had a

valid basis for believing in the cardiovascular safety of Vioxx and that the doctor need not worry about the potential for increased serious cardiovascular thrombotic adverse events in prescribing Vioxx for patients, including patients with established coronary artery disease.

49. The Obstacle Response warned sales reps not to deviate from Merck's script and directed the sales reps to say, "Doctor, let me review the cardiovascular effects section of the VIOXX label," but omitted material elements of the label. It mentioned the total number of patients in the study (Vioxx and naproxen groups combined, preventing the doctor from making even a gross assessment of relative risk), the median age of the patient population and duration of the study, the raw number of cardiovascular thrombotic events for the two treatment groups, and the number of deaths in each group due to cardiovascular thrombotic events along with the assertion that these mortality data were "similar between the treatment groups." The Obstacle Response omitted material information from the Vioxx label, such as:

- VIGOR excluded patients with a predisposition to developing serious cardiovascular problems;
- VIGOR showed a statistically significant greater incidence of serious cardiovascular events in Vioxx patients as opposed to naproxen patients largely due to a difference in the incidence of heart attacks between the groups; and
- the information about VIGOR, as well as two other studies, "should be taken into consideration and caution should be exercised when VIOXX is used in patients with a medical history of ischemic heart disease."

Moreover, the Obstacle Response pointedly omitted any mention of heart attacks. A physician needed to consider all of these omitted data, as well as the FDA's conclusions and cautions, to exercise sound professional judgment about whether to prescribe Vioxx to a patient with established coronary artery disease.

50. Barely one month before Merck pulled Vioxx from the market, it issued its final Obstacle Response on August 26, 2004, in response to a presentation of information from a

massive observational study of Vioxx's cardiovascular safety at the August 2004 International Society for Pharmacoepidemiology Conference. This study estimated that Vioxx had contributed to 27,785 acute heart attacks and sudden cardiac deaths among Americans who had taken the drug between 1999 and 2003. The August 26, 2004 Obstacle Response varied little from the one Merck issued in September 2003, other than the addition of the statement that, "Based on all of the available data, VIOXX remains an excellent choice for your appropriate patients." But Merck did not identify which patients were inappropriate for VIOXX or indicate that additional information was available on which the physician could base that decision.

51. The 2004 Obstacle Response instructed the sales reps to tell doctors that the Vioxx label says the number of "cardiovascular thrombotic events" (forty-five for Vioxx and nineteen for naproxen) was "largely due to nonfatal myocardial infarction (18 vs. 4)." (Emphasis added.) This statement misrepresents the information contained on the cited Vioxx label in at least two respects. First, the label states that these patients suffered "serious cardiovascular thrombotic events" (emphasis added), not just any cardiovascular thrombotic event. Second, the label states that the rate of serious cardiovascular thrombotic events was largely due to "myocardial infarction," not "non-fatal myocardial infarction" as the Obstacle Response asserts. Merck's statement also omits the heart attacks that killed two patients taking Vioxx and falsely implies that patients in VIGOR experienced only non-fatal heart attacks.

52. Through its systematic dissemination to doctors of very carefully edited cardiovascular risk information from the VIGOR study, Merck set out to divert physicians' attention from source information in the VIGOR study or the label and concealed the impact of the valid information about Vioxx's real cardiovascular risk, especially the risk to patients with established coronary artery disease.

53. Merck's New York sales reps received all of the company's Obstacle Responses concerning Vioxx and other communications about how to respond to doctors' questions relating to the cardiovascular safety profile of Vioxx. Merck's New York sales reps communicated the messages contained in those documents to New York doctors in accordance with the company's instructions and directions described above.

Merck's Suppression of VIGOR's Negative Cardiovascular Data in Professional Presentations to Medical Audiences

54. Merck also misrepresented the incidence of heart attacks suffered by Vioxx patients in the VIGOR study in a November 2000 article that had two Merck employees among its authors and was published in the highly regarded, widely circulated, peer-reviewed, professional journal New England Journal of Medicine ("NEJM").

55. In March 2000, Merck received data from VIGOR showing that twenty Vioxx patients had suffered heart attacks thus far in the study, while only four naproxen patients had had heart attacks during the same period. Initially, the draft of the article concerning VIGOR contained a table entitled "CV" events showing numbers of heart attacks. However, two days before the article was submitted to the NEJM, the data was deleted, and the draft was submitted with a blank table. Later drafts, and the final article, reported only seventeen of the twenty heart attacks among the Vioxx patients in the VIGOR study.

56. Thus, though the two Merck employees who were authors of the article were aware of the additional three heart attacks among the Vioxx group no later than July 2000, after five drafts, the final, published version of the article inexplicably failed to include them.

57. Because three of the heart attacks suffered by Vioxx patients were excluded, the article misrepresented the extent of the relative risk of heart attacks among Vioxx patients as compared to naproxen patients.

58. Due to Merck's omission of the actual number of heart attacks among the Vioxx group, doctors who read and relied on this article were deprived of this material and critically important safety information that would have informed their professional judgment concerning the treatment to prescribe for their patients.

59. Another example of Merck's effort to suppress true information as to Vioxx's risks is its threats of retaliation against Dr. Gurkirpal Singh when he raised concerns about the cardiovascular safety of Vioxx. Dr. Singh is a highly regarded Stanford University medical researcher experienced in the types of gastrointestinal issues raised by Vioxx and other pain relievers in its class.

60. In 1999, Merck contracted with Dr. Singh to give lectures and speeches to doctors discussing Vioxx's benefits. After hearing about Vioxx's cardiovascular safety risk as identified in VIGOR, Dr. Singh sought additional data from Merck. Merck did not provide him with such data.

61. Subsequently, Dr. Singh raised his concerns about the cardiovascular safety of Vioxx during his Merck-sponsored presentations to doctors. Dr. Singh's primary scientific contact at Merck described these presentations as "balanced" and stated that his negative information about Vioxx was "scientifically accurate."

62. Merck's Senior Vice-President for Medical and Scientific Affairs reacted to Dr. Singh's presentation by telephoning Dr. Singh's supervisor, a medical professor at Stanford, to complain that Dr. Singh was making irresponsible public statements about Vioxx's cardiovascular effects. The Merck Vice President implied there would be repercussions for the professor and the university if Dr. Singh did not stop making these statements.

63. The Merck Vice President further pressured Stanford, instructing a Merck employee to "[t]ell Singh that we've told his boss about his Merck-bashing" and "should it continue, further actions will be necessary (don't define it)." Following Merck's heavy-handed attempt to suppress a presentation that Merck itself had acknowledged as "balanced" and "scientifically accurate," Dr. Singh terminated his relationship with Merck.

64. The Merck Vice President made similar calls to officials at other university medical schools with staff who had also publicly raised questions about the cardiovascular safety of Vioxx.

Merck's Omission of Negative Cardiovascular Data in Direct-to-Consumer Advertising

65. Merck marketed Vioxx as a safe and effective pain reliever, while diminishing and concealing its increased cardiovascular risk. Using various wording, Merck's press releases issued during 2001 and 2002 consistently told consumers that Merck had -- and therefore they too should have -- confidence in Vioxx's safety profile. In May 2001, despite the results of the VIGOR study, Merck stated that "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx." In April 2002, Merck also told the public that the significance of VIGOR and two other studies was "unknown," creating the misimpression that the highly statistically significant negative cardiovascular thrombotic outcomes from VIGOR were unimportant and of no consequence to an individual taking Vioxx.

66. In September 2001, Merck reiterated its assurance of Vioxx's cardiovascular safety in letters it sent to individual doctors and patients, including those who reside in New York, omitting material information about Vioxx's increased risk of serious cardiovascular thrombotic events, including heart attacks.

67. Merck's massive direct-to-consumer advertising campaign was aimed at having consumers ask their doctors specifically for Vioxx. These ads, which ran in national magazines, failed to provide consumers with material information about Vioxx's cardiovascular dangers. Merck, therefore, encouraged individuals to take Vioxx, including patients with established coronary artery disease.

68. Prior to 2002, Merck's advertisements for Vioxx that appeared in popular magazines and in journals directed at physicians contained no reference to the findings from VIGOR that patients taking Vioxx were at a five-fold increased risk of suffering a heart attack as compared to patients on naproxen and that Vioxx patients' increased risk of experiencing a serious cardiovascular thrombotic event was highly statistically significant.

69. In 2002 and 2003, Merck disseminated advertisements in popular national magazines which, although they referred to VIGOR, failed to allude in any way to the increased risk of serious cardiovascular thrombotic adverse events, and especially to heart attacks, associated with Vioxx. The minimal information about serious cardiovascular thrombotic events they contained was not adequate to put patients with established coronary artery disease on notice that taking Vioxx could be very dangerous for them.

70. The total extent of information related to cardiovascular thrombotic events in these later advertisements consisted of, on the front of the advertisement, a recommendation that patients tell their doctors if they had a history of angina, heart attack or blood clots (variously described as clots in the heart or clots in the body); and on the back of the advertisement, a reiteration of this recommendation, which sometimes came toward the bottom of a long list of ailments that should be mentioned to a doctor, and a statement that serious but rare side effects included heart attacks and similar serious events. But this latter statement failed to communicate the relative risk of heart attack if the patient took Vioxx instead of another effective, readily

available drug. Some New York patients, including those with established coronary artery disease, would not have understood Merck's advertisements as constituting a warning of this specific increased risk of future heart attacks.

E. The Effect of Merck's Suppression, Misrepresentation and Concealment of Vioxx's Cardiovascular Risk

71. Because Merck knowingly and intentionally suppressed, misrepresented and concealed the true cardiovascular dangers of Vioxx and engaged in a unremitting campaign of misinformation about these risks as they were demonstrated by the VIGOR study, as described above, New York physicians prescribed Vioxx for their patients who had established coronary artery disease.

72. New York physicians, like other physicians, operate under a professional obligation to recommend and prescribe only those treatments that are appropriate for the individual patient in light of the patient's medical history and current health status. Conversely, patients rely on the professional judgment of their physicians in deciding whether to consent to and purchase a treatment.

73. Some of the patients who received Vioxx prescriptions that were induced by Merck's suppression, misrepresentation and concealment of material information about Vioxx's cardiovascular risks were New York Medicaid recipients and/or EPIC participants, many of whom had been diagnosed as having coronary artery disease.

74. New York consumers and, on behalf of consumers enrolled in Medicaid and/or EPIC, the New York Medicaid and/or EPIC programs, paid all or part of the cost of Vioxx prescribed to these patients with established coronary artery disease. In the case of such patients who were Medicaid and/or EPIC participants, the relevant program paid claims submitted by the pharmacies that filled these prescriptions for Vioxx.

75. Merck caused New York Medicaid and/or EPIC to reimburse pharmacies from public funds for covered Vioxx prescriptions written for patients with established coronary artery disease. Physicians would not have written these prescriptions if Merck had not suppressed, misrepresented and concealed material information about Vioxx's increased risk of serious cardiovascular thrombotic events.

76. Merck's repeated and persistent fraud in suppressing, misrepresenting and concealing the material information about Vioxx's increased cardiovascular risk created a dishonest marketplace in which doctors and consumers recommended, prescribed or purchased Vioxx for patients for whom it was not an appropriate medication, which injured those consumers, the New York Medicaid and EPIC programs, the State of New York, and the City of New York.

77. New York consumers and the New York Medicaid and EPIC programs do not have an adequate remedy at law that would provide complete relief for Merck's actions described above.

FIRST CAUSE OF ACTION
OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS
(N.Y. Social Services Law § 145-b)

78. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 77 of this complaint.

79. Social Services Law § 145-b provides that "[i]t shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for ... supplies furnished ... pursuant to" the Medicaid Program or EPIC.

80. By engaging in the acts and practices described above, Merck, knowingly made false statements or representations, or deliberately concealed material facts, or engaged in a fraudulent scheme on behalf of itself and others, resulting in the payment and/or overpayment of public funds, in an amount yet to be determined, for Merck's prescription drug Vioxx by the New York Medicaid Program or EPIC in violation of Social Services Law § 145-b.

81. By reason of the foregoing, Merck is liable to the State and the City pursuant to Social Services Law § 145-b for actual damages, as well as for three times the amounts falsely submitted, plus interest at the highest legal rate.

SECOND CAUSE OF ACTION
NEW YORK FALSE CLAIMS ACT
N.Y. Finance Law § 189(1)(a)

82. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 77 of this complaint.

83. The State of New York and the City of New York seek relief against Merck under section 189(1)(a) of the New York False Claims Act, N.Y. Finance Law § 189(1)(a).

84. As set forth above, Merck knowing, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented to agents of the State of New York false or fraudulent claims for payment or approval of Vioxx prescriptions for patients with pre-existing cardiovascular risk factors.

85. The New York State Medicaid and EPIC programs paid such false or fraudulent claims because of the acts or conduct of Merck.

86. By reason of Merck's conduct, the State of New York and the City of New York have been damaged in a substantial amount to be determined at trial.

87. By reason of the foregoing, Merck is liable, pursuant to N.Y. Finance Law § 189(1), to the State for treble damages, penalties, and costs, and to the City for treble damages and costs.

THIRD CAUSE OF ACTION
NEW YORK FALSE CLAIMS ACT
N.Y. Finance Law § 189(1)(b)

88. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 77 of this complaint.

89. The State of New York and the City of New York seek relief against Merck under section 189(1)(b) of the New York False Claims Act, N.Y. Finance Law § 189(1)(b).

90. As set forth above, Merck knowing, or acting in deliberate ignorance or in reckless disregard for the truth, made, used, or cause to be made or used, false records and/or statements to get false or fraudulent claims for Vioxx prescriptions for patients with pre-existing cardiovascular risk factors paid or approved by the New York State Medicaid and EPIC programs.

91. The New York State Medicaid and EPIC programs paid such false or fraudulent claims because of the acts or conduct of Merck.

92. By reason of Merck's false records and/or statements, the State of New York and the City of New York have been damaged in a substantial amount to be determined at trial.

93. By reason of the foregoing, Merck is liable, pursuant to N.Y. Finance Law § 189(1), to the State for treble damages, penalties, and costs, and to the City for treble damages and costs.

FOURTH CAUSE OF ACTION
REPEATED AND PERSISTENT FRAUD
N.Y. Executive Law § 63(12)

94. Plaintiff New York State incorporates by reference the allegations set forth in paragraphs 1 through 93 of this complaint.

95. Executive Law § 63(12) makes "repeated fraudulent ... acts or ... persistent fraud ... in the carrying on, conducting or transaction of business" actionable by the Attorney General.

96. By engaging in the acts and practices described above, Merck has engaged in repeated fraudulent acts or persistent fraud in violation of Executive Law § 63(12).

FIFTH CAUSE OF ACTION
REPEATED AND PERSISTENT ILLEGAL CONDUCT:
OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS
N.Y. Executive Law § 63(12)

97. Plaintiff New York State incorporates by reference the allegations set forth in paragraphs 1 through 93 of this complaint.

98. Executive Law § 63(12) makes "repeated ... illegal acts or ... persistent ... illegality in the carrying on, conducting or transaction of business" actionable by the Attorney General.

99. Merck's violations of N.Y. Social Services Law § 145-b and N.Y. Finance Law § 189(1) constitute repeated and persistent illegal conduct in violation of Executive Law § 63(12).

100. By engaging in the acts and practices described above, Merck has engaged in repeated illegal acts or persistent illegal conduct in violation of Executive Law § 63(12).

SIXTH CAUSE OF ACTION
NEW YORK CITY FALSE CLAIMS ACT
N.Y.C. Admin. Code §§ 7-801 et seq.

101. Plaintiff City of New York incorporates by reference the allegations set forth in paragraphs 1 through 77 of this complaint.

102. The City of New York seeks relief against Merck under sections 7-801 et seq. of the New York City Administrative Code.

103. As set forth above, Merck knowing, or acting in deliberate ignorance or in reckless disregard for the truth, made, used, or caused to be made or used, false records and/or statements to get false or fraudulent Medicaid claims for Vioxx prescriptions for patients with pre-existing

cardiovascular risk factors paid or approved.

104. As set forth above, Merck knowing, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented to agents of the State of New York and the City of New York, false or fraudulent Medicaid claims for payment or approval of Vioxx prescriptions for patients with pre-existing cardiovascular risk factors.

105. The City of New York paid such false or fraudulent Medicaid claims because of the acts or conduct of Merck.

106. By reason of Merck's false or fraudulent claims, records and/or statements, the City of New York has been damaged in a substantial amount to be determined at trial, and seeks treble damages, civil penalties, costs and attorney's fees.

PRAYER FOR RELIEF

WHEREFORE, the People of the State of New York and the City of New York respectfully request that a judgment and order be entered that:

A. Permanently enjoins Merck from engaging in the type of repeated or persistent fraudulent and unlawful practices alleged herein;

B. Directs Merck to pay restitution and damages to all aggrieved consumers, including those not known at the time the order is entered;

C. Directs Merck to pay restitution and damages to the State of New York based on Merck's repeated or persistent fraudulent and illegal practices, for the economic injuries suffered by the New York Medicaid and EPIC programs;

D. Directs Merck to pay to the State of New York and the City of New York damages equal to three times the amount by which the State or any political subdivision, based on Merck's false statement or representation or other fraudulent scheme, overpaid public funds for Merck's prescription drugs under the New York Medicaid or EPIC program;

E. Directs Merck to pay to the State of New York and the City of New York three times the amount of damages sustained because of the acts described herein, pursuant to N.Y. Finance Law § 189(1);

F. Directs Merck to pay to the State of New York civil penalties in the amount of $12,000 for each false or fraudulent claim that Merck caused to be presented to the State of New York in violation of the New York False Claims Act, pursuant to N.Y. Finance Law § 189(1);

G. Directs Merck to pay to the State of New York civil penalties in the amount of $12,000 for each false or fraudulent record or statement that Merck made, used, or caused to be made or used, in order to get a false or fraudulent claim paid or approved in violation of the New York False Claims Act, pursuant to N.Y. Finance Law § 189(1);

H. Directs Merck to pay to the City of New York three times the amount of its damages, plus a civil penalty of $15,000 for each violation of the New York City False Claims Act, Title 7, Chapter 8 of the New York City Administrative Code, §§ 7-801 et seq., plus costs, expenses and attorneys' fees and the cost of the City's investigation;

I. Awards Plaintiffs costs, including additional costs in the amount of $2,000 pursuant to CPLR § 8303(a)(6); and

J. Grants all other relief that is just and proper.

Dated: New York, New York
September 17, 2007

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